भारतीय मानक
Indian Standard

IS 16950 : 2018
(Reaffirmed 2022)

चिकित्सीय वस्त्रादि — एक्स-रे द्वारा पता लगानें योग्य अवशोषक सूती जालीदार कपड़ा — विशिष्टि

Medical Textiles — X-Ray Detectable Absorbent Cotton Gauze — Specification

ICS 11.040.30; 59.080.01

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Technical Textiles for Medtech Applications Sectional Committee, TXD 36

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textile Division Council.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 ‘Rules for rounding off numerical values (*revised*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL TEXTILES —
X-RAY DETECTABLE ABSORBENT COTTON GAUZE — SPECIFICATION

1 SCOPE

This standard specifies performance requirements for X-ray detectable absorbent cotton gauze intended for medical use.

2 REFERENCES

The standards listed in Annex A contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A.

3 TERMINOLOGY

For the purpose of this standard, the following term shall apply.

3.1 X-ray Detectable Absorbent Cotton Gauze — It is absorbent cotton gauze into which is incorporated an X-ray opaque component consisting of a distinctly coloured, continuous, monofilament or multifilament yarn. The X-ray detectable component is securely heat bonded to or is woven into the fabric.

4 WORKMANSHIP AND FINISH

4.1 The X-ray detectable absorbent cotton gauze shall be clean and free from substances liable to cause tendering during storage. The product shall be free from toxic or harmful substances.

4.2 The manufacture and preparation of the cotton gauze shall be conducted under proper hygienic conditions.

5 REQUIREMENTS

The X-ray detectable absorbent cotton gauze shall conform to the requirements specified in Table 1.

Table 1 Performance Requirements for X-ray Detectable Absorbent Cotton Gauze

(*Clause* 5.1)

Sl No. (1)	Characteristic (2)	Requirement (3)	Method of Test, Ref to (4)
i)	Fibre identification	cotton	IS 14944
ii)	Moisture content, percent, *Max*	8	IS 199
iii)	Weight per square metre, g/m^2, *Min*	14	IS 14944
iv)	Threads per dm		IS 14944
	a) Warp	69 to 77	
	b) Weft	53 to 61	
v)	Absorbency (Sinking time in s, *Max*)	10	IS 14944
vi)	*p*H of aqueous extract	6.5 to 7.5	IS 1390
vii)	Water soluble substances, percent, *Max*	0.5	IS 14944
viii)	Residual starch	absent	IS 1967
ix)	Ether soluble substances, percent, *Max*	0.5	IS 14944
x)	Sulphated ash, percent, *Max*	0.4	IS 14944
xi)	Surface active substances	To pass	Annex B
xii)	Extractable colouring matter	To pass	Annex C

Table 1 (*Concluded*)

Sl No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
xiii)	Freedom from optical whitener	No fluorescence (Not more than occasional point of fluorescence visible)	Viewing under ultra-violet light
xiv)	Weight of X-ray detectable thread (g/m^2, *Min)*		
	Monofilament,	0.5	Annex D
	Multifilament,	0.28	Annex D
xv)	Barium sulphate content in X-ray detectable thread percent, *Min*	55 percent	Annex E
xvi)	X-ray opacity	To Pass	IS 14944

6 MARKING

6.1 Each pack of the X-ray detectable absorbent cotton gauze shall be legibly marked with the following information:

a) Name of the product;
b) Manufacturer’s name, initials or trade-mark, if any;
c) Month and year of manufacture;
d) Size; and
e) Any other statutory requirement as required by the law in force.

6.2 BIS Certification Marking

The product may also be marked with the Standard Mark.

6.2.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations made thereunder. The details of the conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

7 SAMPLING AND CRITERIA FOR CONFORMITY

7.1 Lot

All the X-ray detectable absorbent cotton gauze of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot.

7.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

7.1.2 The number of cotton gauze to be selected from the lot shall depend on the size of the lot and shall be in accordance with col 2, col 3 and col 5 of Table 2.

7.1.3 These cotton gauze shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

Table 2 Number of X-ray Detectable Absorbent Cotton Gauze to be Selected

(*Clause* 7.1.2)

Sl No.	Lot Size	Non-Destructive Testing		Destructive Testing	
		No. of cotton gauze to be selected	Acceptance Number	No. of cotton gauze to be selected	Acceptance Number
	N	n	a	n_1	a_1
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13[1)]	1	8	0
ii)	281 - 500	20	2	8	0
iii)	501 - 1 200	32	3	13	0
iv)	1 201 - 3 200	50	5	13	0
v)	3 201 - 10 000	80	7	20	1

[1)] Or lot size when less than 13.

7.2 Number of Tests and Criteria for Conformity

7.2.1 All cotton gauze selected as per col 3 of Table 2 shall be examined for workmanship and finish (*see* **4.1**).

7.2.1.1 Any cotton gauze failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in col 4 of Table 2. Otherwise, the lot shall be rejected.

7.2.2 Out of the sample already found satisfactory according to **7.2.1.1**, a sub-sample as per col 5 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

7.2.3 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective cotton gauze found in the sample (*see* **7.2.2**) is less than or equal to the acceptance number as given in col 6 of Table 2.

8 PACKING

The X-ray detectable absorbent cotton gauze shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed to between the buyer and the seller. Packaging of the product should be such as to maintain the integrity of the product throughout its shelf life.

ANNEX A

(*Clause* 2)

LIST OF REFERRED INDIAN STANDARDS

IS No.	*Title*
IS 199 : 1989	Textiles — Estimation of moisture, total size or finish, ash and fatty matter in grey and finished cotton textile materials (*third revision*)
IS 1390 : 1983	Methods for determination of *p*H value of aqueous extracts of textile materials (*first revision*)
IS 1967 : 1961	Methods for estimation of residual starch in cotton fabrics after desizing
IS 4905 : 2015	Random sampling and randomization procedures (*first revision*)
IS 14944 : 2001	Surgical dressings — Methods of test

ANNEX B

[*Table 1, Sl No. (xi)*]

METHOD OF TEST FOR DETERMINATION OF SURFACE ACTIVE SUBSTANCES

B-1 Shake vigorously in a clean test tube the portion of the aqueous extract reserved before filtration in the test for the *p*H of aqueous extract and examine after 10 min. Not more than a ring of froth, in contact with the walls of the tube remains.

ANNEX C

[*Table 1, Sl No. (xii)*]

METHOD OF TEST FOR DETERMINATION OF EXTRACTABLE COLOURING MATTER

C-1 Slowly extract 10 g in a narrow percolator with ethanol (96 percent) until 50 ml of extract is obtained, pour the liquid into a colourless glass cylinder and examine a 20 cm layer against a white background. A very faint yellow tinge may be observed but no bluish or greenish tinge is apparent.

ANNEX D

[*Table 1, Sl No. (xiv)*]

METHOD OF TEST FOR DETERMINATION OF WEIGHT OF X-RAY DETECTABLE THREAD

D-1 Weight of X-ray detectable multifilament/ monofilament yarn are determined by carefully removing the yarn from the material being examined and measuring its length and weight.

ANNEX E

[*Table 1, Sl No. (xv)*]

ESTIMATION OF BARIUM SULPHATE IN X-RAY DETECTABLE THREADS

E-1 REAGENTS USED

a) Ammonium sulphate : 5 percent solution in 1 N Hydrochloric acid (HCl).

b) Tetramethylammonium hydroxide : 25 percent aqueous solution (TMAH).

c) Ethylenediaminetetraacetic acid diammonium salt 5 percent in water (ammonium EDTA).

E-2 METHOD

Take 1 g of sample in silica beaker. Dry the sample at 95°C and ash in a muffle furnace at 600°C for at least 3 h. Add 10 ml of acid ammonium sulphate and 30 ml of water to the ashes sample and warm to dissolve soluble material. Decant the contents with washing into a 50 ml centrifuge tube, the barium sulphate ($BaSO_4$) being washed into the tube as far as possible. Centrifuge the tube for 5 min, decant the supernatant and the tube allowed to drain, same process repeated once again. Meanwhile add 10 ml of ammonium EDTA and 3 ml TMAH to the silica beaker and warm on a steam bath for 10 min to dissolve $BaSO_4$, transfer the contents to tube with washing, and place on a boiling water bath for about 10 min with occasional stirring. The solution is cooled, made up to 1 000 ml then take 1 ml made up to 1 000 ml and filtered (if necessary) before ICP-MS which is carried out in the usual manner.

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Amendments Issued Since Publication

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